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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/026,698 | 12/27/2001 | Naganori Numao | 21776/0066 | 9270 |
| 30678 | 7590 | 01/16/2004 | | |
| CONNOLLY BOVE LODGE & HUTZ LLP SUITE 800 1990 M STREET NW WASHINGTON, DC 20036-3425 | | | EXAMINER LY, CHEYNE D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/026,698 | Applicant(s) NUMAO, NAGANORI | |
| | Examiner Cheyne D Ly | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☒ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3 and 11-13, drawn to a method for predicting biological functional activity and/or binding activity of a protein, classified in class 702, subclass 19. If this Group is elected, then the below summarized 2 species sets (A and B), election of a species from each set is required.
 - II. Claims 4 and 11-13, drawn to a method for predicting biological functional activity and/or binding activity of a nucleotide sequence, classified in class 702, subclass 20. If this Group is elected, then the below summarized 1 species set (A), election of a species from each set is required.
 - III. Claims 5 and 6-13, drawn to a method for predicting biological functional activity and/or binding activity of an amino acid and other nucleotide sequence, classified in class 702, subclasses 19 and 20. If this Group is elected, then the below summarized 3 species sets (A-C), election of a species from each set is required.
 - IV. Claim 14, drawn to a binding mode of at least two kinds of proteins or, nucleotides, classified in class 702, subclasses 19 and 20. If this Group is elected, then the below summarized 3 species sets (A-C), election of a species from each set is required.
 - V. Claim 15, drawn to an application of biological functional activity of a protein or nucleotide sequence, classified in class 702, subclasses 19 and 20. If this Group

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is elected, then the below summarized 4 species sets (A-D), election of a species from each set is required.

SPECIE ELECTION REQUIREMENT

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

FOR ALL GROUPS:

Species (A):

3. Species of natural-type or non-natural-type are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select a natural-type or non-natural-type.

4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-15 are generic to the above species in all Groups.

FOR GROUPS I and III-V:

Species (B):

5. Species of motifs are cited in claims 2 and 6, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select an unspecified type of motif or a type of motif from those listed in claim 2 and

6.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3 and 5-13 are generic to the above species in all Groups.

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FOR GROUPS III-V

Species (C):

6. Species of amino acid or nucleotide sequence are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select an amino acid or nucleotide sequence.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5, 6, and 7-15 are generic to the above species in all Groups.

FOR GROUP V

Species (D):

8. Species of employment for activities are cited in claim 15, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select a type of employment activity from those listed in claim 15.

9. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 15 is generic to the above species in all Groups.

10. Applicant is advised that a reply to this requirement must include an identification of a specie from list of specie sets cited above that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument

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that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. The inventions of Groups I-III are distinct inventions because they are directed to different methods regarding the critical limitations therein. For Group I, the critical feature is a method for predicting biological functional activity and/or binding activity of a protein. For Group II, the critical feature is a method for predicting biological functional activity and/or binding activity of a nucleotide sequence. For Group III, the critical feature is a method for predicting biological functional activity and/or binding activity of an amino acid and other nucleotide sequence. The completely distinct critical features of each Group support the undue search burden if they were examined together.

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14. Inventions of Group IV and [I-III] are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)). In the instant application, the binding mode of Group IV may be generated by any of the methods of Groups I-III, or alternatively, by using X-ray crystal structure data. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

15. Inventions V and [I-III] are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)). In the instant application, the activity of Group V may be generated by any of the methods of Groups I-III, or alternatively, by using X-ray crystal structure data. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


18. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

21. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
12/30/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER